2501304115

To : Pauline Rozen

From : Manuel Bourlas

Date : 28.06.94
Time : 12:33:43

Subject : LEE & GARMENT / FDA WHITE PAPER: COMMENTS +

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*** Forwarding note from MBOURLAS--VCH0021A 28.06.94 12:27 ***
To: MFIRESTO--VCH0021A Marc Firestone

From: Manuel Bourlas
Subject: LEE & GARMENT / FDA WHITE PAPER: COMMENTS +

Please find my comments below:

1. Bottom of page 2, top of page 3: The reference to wine and ice cream are good examples but I wonder if it raises the question of what the "real" cigarette manufacturers "intent" is. Projecting a bit:

"Cigarettes can become 'additive' satisfying an individuals habit, but no manufacturer intends such a thing."

2. Bottom of page 4: "The courts... Are there any examples of a product actually being classified as a drug based on consumer's exclusive use for drug-like purposes?? No!.

3. Top of page 5, end of first paragraph: "... to be used as a drug (or show that the customer is using it for drug-like purposes)??

4. Middle of page 6 and page 8 under "tolerance": "A tendency to increase the dose;.." Also entire first paragraph on page 9:

Tolerance implies smoking ever-increasing number of cigarettes. I wonder if the following could help as arguments:

a) If people smoke for nicotine, how does one explain the continuous reduction of the Sales Weighted Average? We could certainly show this to be the case in the developed markets around the world.

b) If people smoke for nicotine, how does one explain the significant switching which has taken place towards lower "tar"/nic products? This could also be shown for a variety of international markets.

c) If tolerance is in force in cigarette smoking, how does one explain the nearly constant "per-capita-consumption" figures in the developed markets? I do not know if this is the case, but I seem to remember that the figures were relatively constant for our European markets.

5. Bottom of page 6: "It accepted "the" broader..." I would change the word "the" to "a". "The" is too precise, and anyway, he may decide to change it once again!!

Note: Actually it is quite tricky/shifty to change the definition to be able to include nicotine. Where else in the scientific world do we change definitions (long standing ones) to fit our needs. If this were the case, we would be redefining words continuously.

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7. Page 8, paragraph beginning with "Nicotine is not an intoxicant..."

Although the examples are relevant, I seem to remember studies being conducted which measured the alertness and responsiveness of individuals. Might this be of use in this paragraph. On the other hand, ...

Cont...

Source: https://www.industrydocuments.ucsf.edu/docs/ynlx0000